

REMARKS

Claims 30-42, 45 and 48 are amended as discussed below. It is respectfully submitted that the present amendment presents no new issues or new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

I. Examiner's Initial Requested On Information Disclosure Statement

The Examiner is respectfully requested to initial the references submitted on the Information Disclosure Statement. The Examiner's initials were placed next to the first foreign patent document, but the Examiner did not initial the other foreign patent documents.

II. Specification

The Examiner indicates that the specification uses trademarks on, e.g., 18-19 and 21. Upon review of these pages of the specification, it is respectfully submitted that the trademarks are properly identified by the use of the designation "TM."

III. The Rejection of Claims 48 and 49 under 35 U.S.C. 101

Claims 48 and 49 are rejected under 35 U.S.C. 101. The Examiner states that these claims can read on an integral part of a human being, which is non-statutory subject matter. The Examiner suggests amending the claim to recite an "isolated" host cell.

The claims have been amended as suggested by the Examiner.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 101. Applicants respectfully request reconsideration and withdrawal of the rejection.

IV. The Rejection of Claims 30 and 31-49 under 35 U.S.C. 112

Claims 30 and 31-49 are rejected under 35 U.S.C. 112 as indefinite. The Examiner alleges that the phrase "comprising an amino acid sequence" is indefinite because it is not clear whether the claims encompass a polynucleotide comprising a fragment or subsequence of the polypeptide that "is 8% [sic 80%] identical to amino acids 22-450 of SEQ ID NO:4 or polypeptides comprising the full length of amino acid sequences that are 80% identical to SEQ ID NO:4." The Examiner suggests amending the claim to recite "comprising the amino acid sequence." This rejection is respectfully traversed.

It is not clear how the Examiner has reached a different interpretation of the claims based

on whether the article "an" versus "the" is used in the context of the present claim. The claims require a certain percentage of sequence identity to a reference sequence. Sequence identity is determined by aligning the sequences using the Smith-Waterman alignment, and then calculating the identity using the recited computer program. See the specification at page 4, line 25 to page 5, line 6. Different sequences are not covered by substituting "the" for "an" as the sequence either has or does not have the recited identity when carrying out the sequence identity determination as instructed by the specification. Moreover, the claims also require that the polypeptide have alpha-amylase activity, so not all fragments are covered as the fragment would have to be an alpha-amylase.

Thus, the scope of these phrases is identical and it is not seen why the change requested by the Examiner is warranted. Moreover, the current wording of the claim is proper because use of the article "an" instead of "the" is proper when the element is first introduced in the claim. Accordingly, the phrase "an amino acid sequence" is proper because antecedent basis had not yet been established for "the amino acid sequence."

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 112. Applicants respectfully request reconsideration and withdrawal of the rejection.

V. The Rejection of Claims 30 and 31-39 under 35 U.S.C. 112

Claims 30 and 31-49 are rejected under 35 U.S.C. 112, as indefinite. This rejection is similar to the rejection above in that the Examiner alleges that the phrase "encoded by a polynucleotide comprising a nucleotide sequence" is not clear because it is not clear whether this encompasses the full-length sequence comprising the nucleic acid sequence shown from positions 68-1417 of SEQ ID NO:3 or any portion, fragments of sequence from position 68-1417 SEQ ID NO:3. The Examiner suggests amending the claims to read "comprising the polynucleotide sequence." This rejection is respectfully traversed.

It is also not clear what distinction the Examiner is making between "comprising a nucleotide sequence" as compared to the phrase "comprising the nucleotide sequence" and how this leads to the conclusion that different sequences are covered. As with the polypeptide sequences, different polynucleotide sequences are not covered by substituting "the" for "a" as the sequence either has or does not have the recited identity when carrying out the sequence identity determination as instructed by the specification.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 112. Applicants respectfully request reconsideration and withdrawal of the rejection.

VI. The Rejection of Claims 30 and 31-49 under 35 U.S.C. 112

Claims 30 and 31-49 are rejected under 35 U.S.C. 112 as indefinite. The Examiner alleges that adding the term "sequence" before "identity" is necessary to clarify the metes and bounds of the claims. This rejection is respectfully traversed.

Again, the addition of the term "sequence" does not add any additional clarity to the claims. Based and the claims and the specification, the claims are clearly referring to the identity between two nucleotide sequences or two amino acid sequences. However, in order to expedite prosecution, Applicants will add the term "sequence" before "identity."

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 112. Applicants respectfully request reconsideration and withdrawal of the rejection.

VII. The Rejection of Claims 30 and 31-49 under 35 U.S.C. 112

Claims 30 and 31-49 are rejected under 35 U.S.C. 112 as indefinite. The Examiner says that the phrase "shown fromSEQ ID NO" is not clear. The Examiner states that it is not clear whether the isolated polypeptide or polynucleotide actually has the recited sequence or whether it is a representative sequence. The Examiner suggest that Applicants make a direct reference to the sequence such as "polypeptide sequence from position 22-450 of SEQ ID NO:4 or "polynucleotide sequence from position 68-1417 of SEQ ID NO:3." This rejection is respectfully traversed.

It is respectfully submitted that the use of the term "shown" may be redundant, but it clearly does not make the claims indefinite. Nevertheless, in order to expedite prosecution Applicants will amend the claims to delete this redundant language.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 112. Applicants respectfully request reconsideration and withdrawal of the rejection.

VIII. The Rejection of Claims 30 and 31-49 under 35 U.S.C. 112

Claims 30 and 31-49 are rejected under 35 U.S.C. 112 as lacking enablement. The Examiner states that the claims require *E. coli* strain DSM 15334 to practice the claimed invention. The Examiner states that a statement indicating that the biological material is readily available must be provided.

Submitted herewith is a Statement under 37 C.F.R. 1.808, complying with the deposit requirements.

For the foregoing reasons, Applicants submit that the claims overcome this rejection. Applicants respectfully request reconsideration and withdrawal of the rejection.

VIX. The Rejection of Claims 30 and 31-49 under 35 U.S.C. 112

Claims 30-49 are rejected under 35 U.S.C. 35 U.S.C. 112 as lacking enablement. The Examiner alleges that the claims are not enabled for a polynucleotide having 80% to 95% nucleic acid sequence identity with nucleic acid sequence from position 68-1417 of SEQ ID NO:3 or a polynucleotide encoding an amino acid sequence having 80% to 95% sequence identity with amino acids 22-450 of SEQ ID NO:4. This rejection is respectfully traversed.

Initially, it is submitted that claims 43, 44 and 45 should not have been included in this rejection. These claims, as shown below, recite a specific polynucleotide sequence. These claims are clearly enabled.

Claim 43. The polynucleotide according to claim 30, wherein the polypeptide consists of an amino acid sequence having amino acids 22 to 450 of SEQ ID NO:4.

Claim 44. The polynucleotide according to claim 30, wherein the polypeptide consists of an amino acid sequence encoded by the amylase encoding part of the polynucleotide inserted into a plasmid present in the *E. coli* host deposited under the Budapest Treaty with DSMZ under accession number DSM 15334.

Claim 45. The polynucleotide according to claim 30, wherein the polypeptide is encoded by a polynucleotide consisting of a nucleotide sequence shown from position 68 to 1417 in SEQ ID NO:3.

With respect to the claims having a broader scope, in particular, claims 30-42 and 46-49, it is respectfully submitted that these claims are also enabled. As acknowledged by the Examiner, "enzyme isolation techniques, recombinant and mutagenesis techniques are known in the art and it is routine in the art to screen for multiple substitutions or multiple modifications." The specification provides a description of many of these routine tasks. See the specification at page 7, line 14 to page 8, line 16. It is also routine in the art to make conservative amino acid substitutions which can generally be expected to preserve the structure and function of the molecule. Thus, an artisan can clearly use these tasks to produce, e.g., variants of the new sequence discovered by Applicants.

The claims recite a degree of identity of 80%, 85%, 90% and 95%. Based on the high degree of identity recited in the claims, the polynucleotides falling within the scope of the claims

encode alpha-amylase which have a very high degree of structural similarity to the reference sequence. As such, an artisan would have a reasonable expectation of being able to practice the claimed invention commensurate in scope with the claims as an artisan is routinely able to obtain, using the reference sequence as a starting point, highly homologous sequences therefrom. Indeed, the level of skill in the relevant art is very high. Thus, once apprised of Applicants' invention, it is simply routine to practice the invention, using, for example, well-known molecular biological techniques used for obtaining highly homologous nucleic acids and polypeptides. Indeed, one skilled in the art would have a very high degree of predictability of being able to make such sequences. That is, once provided with this new sequence, Applicants have enabled the skilled artisan to practice the invention by producing highly homologous polynucleotides encoding alpha-amylases.

Furthermore, the test for determining enablement is not whether *any* experimentation is required, but rather whether *undue* experimentation is required. Indeed, and as noted by the *In re Wands* court (*In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)), the test for determining whether undue experimentation is required even permits a considerable amount of testing. The experimentation that would be required by the present invention is clearly not undue, but rather involves only routine molecular biological techniques. Accordingly, even though the experimentation involved might be time consuming, it is the *nature* and not the *amount* of experimentation that is determinative of non-enablement. See *Hybritech v. Monoclonal Antibodies, Inc.*, 231 USPQ 81 (Fed. Cir. 1986).

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 112. Applicants respectfully request reconsideration and withdrawal of the rejection.

X. Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,



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Date: August 21, 2006